STATUS OF CLAIMS

Claims 1-39 are pending in the application. Claims 23-39 were previously withdrawn from consideration pursuant to a restriction requirement. Thus, claims 1-22 are currently under examination. Applicant has added amended independent claim 1 and added new claims 40-41. Support for the amended claim 1 is found in original claims 1, 31, and 32 and paragraph [0009] of the specification. Support for new claims 40-41 is found in the original claims and in the specification as filed. Specifically, support for new claim 40 is found in original claim 17 and paragraph [0019] of the specification. Support for new claim 41 is found in original claim 18 and paragraph [0019] of the specification. There is no issue of new matter.

REMARKS

Rejection Under 35 U.S.C. 112, second paragraph

Applicants acknowledge the Examiner's withdrawal of the rejection under 35 U.S.C. 112, second paragraph.

Rejection for Non-Statutory Obviousness-Type Double Patenting

Applicants gratefully acknowledge the Examiner's acceptance and recordation of a terminal disclaimer on May 1, 2008, obviating the double patenting rejection.

Rejection under 35 USC § 103(a) over Michal et al. and Sogo et al.

Claims 1-22 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Pat. No. 6,287,285 (Michal et al.) in combination with the article, "S-Nitrosothiols cause prolonged, nitric oxide mediated relaxation in human saphenous vein and internal mammary artery: therapeutic potential in bypass surgery" by Sogo et al.

In response, Applicants respectfully traverse the rejections and their accompanying remarks. The prior art references, in combination, fail to teach or suggest ***all*** the claim limitations. In addition, the teaching or suggestion to make the claimed combination and the reasonable expectation of success are not both found in the prior art,

but rather, upon Examiner's own assumptions. This is contrary to the legal requirements set forth in *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991) requiring that the teaching or suggestion and the reasonable expectation of success be found in the prior art and not the applicant's disclosures.

As amended, independent claim 1 provides for a medical article comprising:

a first polymer matrix having a first nitric oxide donor compound disposed within the first polymer matrix, a second polymer matrix having a second nitric oxide donor compound disposed within the second polymer matrix. The second nitric oxide donor compound differs from the first nitric oxide donor compound, and the first polymer matrix is chemically distinct from the second polymer matrix. The medical article is adapted, after placement at a delivery position on or within the body of a patient, for local delivery of the first nitric oxide donor compound and a nitric oxide product of the first nitric oxide donor compound and for local delivery of the second nitric oxide donor compound and a nitric oxide product of the second nitric oxide donor compound.

The claimed invention is structurally different from the device of Michal et al. Michal et al. Michal et al. does not teach a device having a first and second polymer matrix having the two different nitric oxide donor compounds. Sogo et al. does not remedy this deficiency and merely provides experimental data on various S-nitrosothiol compounds.

In addition, Michal et al. fails to teach the claimed NO donor compounds. Specifically, Michal et al. fails to teach a *combination of two different NO donor compounds* in a single medical device. The Examiner merely states that one of skill in the art would make the combination without offering any reference or teaching or suggestion within the cited prior art themselves that would support this assumption.
Indeed, the Examiner admits that "the reference *does not explicitly teach* the combination of S-nitroso-N-acetyl-D,L-pencillamine and S-nitrosoglutathione" (emphasis added). Michal et al. fails to provide any explicit statement of using a combination of NO donor compounds. Indeed, Applicants assert that Michal et al. does not even "suggest" inclusion of more than one NO donor compounds, and the only passage of Michal et al. that the Examiner turns to support her argument that Michal et al. "suggests" such a

combination is Claim 20 of Michal et al., which claims: "The coated device of claim 1 wherein the therapeutic or diagnostic agent comprises one or more nitrogen oxide donating compounds selected from the group consisting of 2-methyl-2-nitrosopropane, S-Nitroso-N-acetyl-D,L-penicillamine, 3-morpholoinosydoimine, sodium nitrate, s-nitrosoglutatione, sodium nitroprusside, and nitroglycerine."

The secondary reference, Sogo et al. does not remedy this deficiency. It also, does ***not*** teach a combination of NO donor compounds. The Examiner asserts that one of ordinary skill in the art may be "motivated by the teaching of Sogo et al. that these two NO donor compounds produce more relaxation of vessel walls than commonly used NO donors with prolonged sustained relaxation and dilatation of human arteries, and their use might improve the outcome of coronary artery bypass." Applicants assert that conclusion is erroneous and utterly unsupported by the teachings of Sogo et al.

Sogo et al. presents nitrosoglutathione and N-(S-nitroso-N-acetylpenicillamine) as *alternatives*, rather than *as a combination*. Nowhere does Sogo et al. teach or even suggest of using *both NO donors in conjunction with one another.* This is evidenced by all of the examples and experimental results in Sogo et al., in which response curves for RIG200 (N-(S-nitroso-N-acetylpenicillamine) are *separate and distinct* from response curves for GSNO (nitrosoglutathione) and there are no data or textual support for a combination of two or more NO donor compounds. (*See* Figures 3, 4, 5, 6, and their accompanying text).

The addition of the disclosure of Sogo et al. to that of Michal et al. on its face relies upon the use of undue hindsight, which is prohibited. *See Akso N.V. v. U.S. International Trade Commission*, 808 F.2d 1241, 1480-81, 1 U.S.P.Q.2d, 1241, 1246 (Fed. Cir. 1986), *cert. denied,* 482 U.S. 909 (1987), *Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861, 874, 228 U.S.P.Q. 90-99 (Fed. Cir. 1985). Also see MPEP § 2142, second paragraph. It assumes that one of ordinary skill in the art would have recognized the synergism that results from employing more than one NO donor compound simultaneously in a single device. Unfortunately, this knowledge is only based upon ***applicant's own disclosure*** and nothing within the four corners of either Sogo et al. or Michal et al. Thus, the combination must fail.

Finally, the teachings of the references are not properly combinable without motivation and suggestion to combine them found in the references themselves. In re Jones, 958 F.2d 347, 351, 21 U. U.S.P.Q.2d 1941, 1943-44 (Fed. Cir. 1992), In re Fine, 837 F.2d 1071, 1075, 5 U.S.P.Q.2d 1596, 1598-99 (Fed. Cir. 1988). Given the disclosures in Sogo et al. that certain nitrosothiol compounds work well in production relaxation in veins and arteries, as the Examiner readily admits, there would be no motivation for one of ordinary skill in the art to suppose a deficiency in the individual compounds that would motivate him to formulate a remedy to boost the desired activity of the individual compounds. Nothing within Sogo et al. even hints that a single nitrosothiol compound is insufficient.

The Examiner further argues that "the combination of the references teaches the same first nitric oxide donor and second nitric oxide donor as instantly claimed, therefore, the half-life, activity, release rates, and susceptibility to metal ion catalyst release are expected to be the same as those recited by the instant claims." Regarding this conclusion, it is respectfully submitted that the Examiner appears to be relying on inherency to remedy the deficiency of the combined references in teaching a combination of NO donor compounds. However, that which is inherent in the prior art, if not known at the same of the invention, cannot form a proper basis for rejecting the claimed invention as obvious under 35 U.S.C. §103. *See In re Shetty*, 566 F.2d 81, 86, 195 U.S.P.Q. 753, 756-57 (C.C.P.A. 1977).

Since there is neither an express disclosure of the elements of Applicants' claimed invention nor a reasonable basis for a conclusion of inherency, reconsideration and withdrawal of the rejection of the claims under 35 U.S.C. § 103(a) is respectfully requested. The courts have been clear that there must be some ***articulated reasoning with some rational underpinning*** to support the legal conclusion of obviousness. *In re Kahn,* 441 F.3d 977, 988 (Fed. Cir. 2006), *cited with approval in, KSR Int'l v. Teleflex, Inc.*, 127 S. Ct. 1727, 1740-41, 82 USPQ 1385, 1396 (2007). Applicants state that the Examiner has not provided a rational underpinning to support the combination of two different NO donor compounds.

In light of the above remarks, reconsideration and withdrawal of this rejection of the claims under 35 U.S.C. § 103 is respectfully requested.

For at least these reasons, Applicant respectfully submits that the claims are patentable over the cited references. Given the above remarks and the Terminal Disclaimer submitted herein, Applicant states that the Examiner's rejection under 35 U.S.C § 103(a) and the non-statutory double patenting rejection have been obviated and Applicant respectfully requests that the Examiner withdraw the rejections.

CONCLUSION

Applicants respectfully submit that all pending claims are in condition for allowance, early notification of which is earnestly solicited. Should the Examiner be of the view that an interview would expedite the application at large, request is made that the Examiner telephone the undersigned attorney at (908) 518-7700, ext. 7 in order to resolve any outstanding issues.

FEES

The Office is authorized to charge the $810.00 fee for a Request for Continued Examination, the $1,110.00 fee for a three-month extension of time and the fee of $104.00 for two addition claims to deposit account number 50-1047. The Office is further authorized to charge any additional fees required, or credit any excess, to deposit account number 50-1047.

Dated: February 2, 2009

Respectfully submitted,

/Keum J. Park/

Keum J. Park
Registration No. 42,059

Attorney for Applicants
Mayer & Williams PC
251 North Avenue West, 2nd Floor
Westfield, NJ 07090
Tel.: 908-518-7700, ext. 7
Fax: 908-518-7795